Defining Costs that Drug Producers & Other Stakeholders are Responsible For

Synopsis: As the Board of Health considers secure medicine return, it must define how responsibility for costs of the product stewardship program are assigned to producers and to other stakeholders. In a product stewardship model, producers have the primary responsibility as the entity with the greatest ability to internalize costs (ie to work program costs into their business model), however other stakeholders in the life cycle of a product also have roles and responsibilities. Product stewardship legislation typically defines costs that stakeholders are responsible for.

Examples of Cost Categories for a Medicine Take-back System:

1. *Collection*
   - Secure Metal Drop Boxes
   - Collection Supplies
   - Staff Time at Collection Site
   - Pre-paid mailers and distribution (if utilized)
2. *Transportation to Interim Storage at Central Warehouse (if needed based on program design & operation)*
   - Transportation to Central Warehouse
   - Law Enforcement Escort for Consolidation (currently required for controlled substances)
   - Warehousing of Medicines
3. *Transportation & Final Disposal*
   - Transportation to Final Disposal Facility
   - Law Enforcement Escort to Final Disposal Facility (currently required for controlled substances)
   - Disposal at Properly Permitted Incineration Facility
4. *Programmatic*
   - Administration
   - Promotion & Evaluation
5. *Agency Oversight & Enforcement*

Considerations for this decision include:

- How to define producers as primarily responsible for reasonable costs of providing the medicine take-back system, while appropriately assigning shared roles to other stakeholders.
- Ensuring that responsibilities are clearly defined to avoid ambiguity, ie is stating producers are responsible for "costs of collection, transportation, and disposal" sufficiently clear, or do those costs categories require further description.
- Product stewardship policies are usually silent on how producers may internalize costs, leaving that up to the producers. Businesses can always pass costs on to consumers, so this does not need to be specified in the legislation; however, it is a common question.
- Addressing concerns that the costs of medicine take-back will be used as reason for disproportionate increases in costs of medicines.

Policy decisions to be made:

1. **Identify costs that producers are required to pay. Identify any shared cost responsibilities for other stakeholders, such as collectors and local governments.**

Cost Category	Costs drug producers are responsible for	Costs that other stakeholders are responsible for
1. Collection		
2. Transportation to Interim Storage at Central Ware house		
3. Transportation & Final Disposal		
4. Programmatic		
5. Agency Oversight & Enforcement		
6. Other?		

2. Define whether producers are allowed to charge residents fees for the program.

Example policy language for consideration:

> "No Person or Producer may charge a specific point-of-sale fee to consumers to recoup the costs of their Product Stewardship Program, nor may they charge a specific point-of-collection fee at the time the Unwanted Products are collected from Residential Generators or delivered for disposal."
> – from Alameda County Safe Drug Disposal ordinance.
>
> "Producers may not impose a visible fee on consumers when covered drugs are purchased or returned."
> – from WA State medicine take-back bill SSB 5234.

Considerations:

- Product stewardship policies often forbid end-of-life charges for recycling or disposal of a product because they are an obvious deterrent to use of the program by residents.
- Some product stewardship policies specify no visible fee at point of sale. Other product stewardship policies specifically allow handling fees to be passed through to consumers, or defined at point of sale. In general, WA retailers do not support mandatory, visible point of sale fees due to burdens fees create for them.

3. Decide whether to define a limit to cost responsibilities through a program cost cap.

The legislation could:

A. Not define a cost cap. Producers would be responsible for all costs assigned to them by the legislation, whatever the amount.
B. Define a cost cap in one of several ways, for example:
    - set cap at a specific dollar amount, indexed to inflation.
    - set cap at a defined amount per prescription dispensed and per container of OTC medicine sold in the county.
    - set cap at a defined percentage of annual medicine sales in the county.

Considerations:

- Pro's: clarifies that the total cost to producers is a reasonable amount; helps address concerns from public or stakeholders about likelihood of increase in cost of medicines.

- Con's: setting too low a cap will result in underfinanced program; financial audits will be required to verify claims that expenses had reached the cost cap; indexing the cap to sales data is complicated by limits to available sales data.

Attachments:

- Examples of Actual Medicine Take-back Program Costs
- King County-wide Medicine Take-back System Cost Estimate & Comparison to Unit Sales of Medicines
- Medicine Sales in King County, WA State, and U.S. (2011) and Estimated Amount of Leftover Medicines
- Pharmaceutical Product Stewardship Policy Comparison Table: item #3 "Who pays for and provides the program?"